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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/325,095	06/03/1999	IAN D. HILES	LUD5246.4JEL	2392

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EXAMINER

HINES, JANA A

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 01/15/2003

20

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/325,095

Applicant(s)

HILES ET AL.

Examiner

Ja-Na A Hines

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM
THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 February 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 51-61 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 51-61 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

1. Applicant's request for reconsideration of the finality of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

2. In view of the response filed on June 13, 2002 PROSECUTION IS HEREBY REOPENED. New Grounds of rejection are set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

- (a) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,
- (b) request reinstatement of the appeal.

If reinstatement of the appeal is requested, such request must be accompanied by a supplemental appeal brief, but no new amendments, affidavits (37 CFR 1.130, 1.131 or 1.132) or other evidence are permitted. See 37 CFR 1.193(b)(2).

Amendment Entry

3. The amendment filed February 2, 2002 has been entered. Examiner acknowledges amendments to the specification. Claims 39-50 have been canceled. Claims 51-61 have been newly added and are under consideration in this office action.

Drawings

4. Applicant is required to submit a proposed drawing correction in reply to this Office action as cited on the PTO-form 948. The drawings corrections will no longer be held in abeyance.

Withdrawal of Rejections

5. The following rejections are withdrawn in view of either applicant's arguments and/or amendments:

a) the rejection of claims 39-50 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention;

b) the rejection of claims 39-50 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention;

c) the rejection of claims 39-50 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention;

d) the rejection of claims 39-50 under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps; and

e) the rejection of claims 39-47 and 49-50 under 35 U.S.C. 103.

Response to Arguments

6. Applicant's arguments with respect to claims 39-50 have been considered but are moot in view of the new ground(s) of rejection.

NEW GROUNDS OF REJECTION

Claim Objections

7. Claim 58 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of previous claim 51. In view of the method for expressing a gene, the sample is already RNA, thus claim 58 fails to further limit the claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 51-61 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to

reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Claim 51 is drawn to a method for determining expression of a gene that encodes a human polypeptide that has PI3 kinase activity and a molecular weight of about 110 kD comprising contacting a sample with a nucleic acid molecule and determining hybridization as a determination of expression of said gene. Claim 59 is drawn to a method for determining if a cell contains a gene which encodes a human polypeptide which has PI3 kinase activity comprising similar steps.

The specification and claims lack sufficient written description of the DNA that must hybridize. There is no description of the DNA that must encode a gene that encodes a human polypeptide. The instant specification does not provide for the gene structure, i.e., introns and exons. The specification does not provide a teaching of the entire gene structure, showing that the gene was isolated at the time the invention was made. The specification does not contain a structural characterization of the complete gene sequence. There is not an adequate description of the DNA to which the nucleic acid must hybridize. There is no description of the DNA which encodes said gene. Since the claim language embraces lots of variants and there is no description of the DNA which encodes such, the description is insufficient since there is no structure described.

Moreover, a nucleic acid molecule is described by its activity of function, i.e., the ability to specifically hybridize to a transcript of said gene, is not sufficient to define the

Art Unit: 1645

nucleic acid molecule itself. The description of the ability of the claimed nucleic acid to specifically hybridize to a transcript of said gene may describe the nucleic acid molecules function; it does not describe the nucleic acid itself. The hybridization distinction is a purely functional distinction. Thus, a description of the nucleic acid molecule by what it does, such as hybridizing to a transcript is insufficient.

The specification does not provide evidence that any nucleic acid molecule, as claimed, functions with the ability to hybridize to a transcript. In view of the lack of evidence, it is apparent that Applicants were not in possession of additional nucleic acid molecules which hybridize specifically to a transcript of said gene, at the time of filing the instant application. With the exception of molecules identified in claim 56, the skilled artisan cannot envision the detailed structure of the nucleic acid molecule, thus conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. An adequate description requires more than a mere statement that it is part of the invention. The nucleic acid itself is required. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016. The hybridization distinguishes the claimed nucleotide sequences from unclaimed sequences only by what they do, which is a purely functional distinction. Even where there is an actual reduction to practice, which may demonstrate possession of an embodiment of an invention, it does not necessarily describe what the claimed invention is. The instant specification and claims fail to describe a nucleic acid molecule, it is noted that the function of the nucleic acid does not describe the claimed nucleic acid molecule itself.

See also, *In The Reagents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), where the court held that a generic statement that defines a genus of nucleic acids by only their functional activity does not provide an adequate description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA...requires a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention".

Thus, in the absence of sequence information of the nucleic acid molecule or the encoded gene described only by its ability to hybridize fails to meet the written description requirements. In view of these considerations, a person of skill in the art would not have viewed the teachings of the specification sufficient to show that Applicants were in possession of the nucleic acid molecules as instantly asserted. Therefore the full breadth of the claims fails to meet the written description provision of 35 USC 112, first paragraph.

New Matter Rejection

9. Claims 51-61 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the

Art Unit: 1645

application was filed, had possession of the claimed invention. This is a new matter rejection.

Claim 51 is drawn to a method for determining expression of a gene wherein the gene encodes a human polypeptide that has PI3 kinase activity and a molecular weight of about 110 kD comprising contacting a sample with a nucleic acid molecule which specifically hybridizes to a transcript of said gene at the recited conditions followed by washes and determining said hybridization as a determination of expression of said gene.

Claim 59 is drawn to a method for determining if a cell contains a gene wherein the gene encodes a human polypeptide that has PI3 kinase activity and a molecular weight of about 110 kD comprising contacting a sample with a nucleic acid molecule which specifically hybridizes to a transcript of said gene at the recited conditions followed by washes and determining said hybridization as a determination of the presence of said gene.

There appears to be no teaching within the specification that the determination of hybridization alone will determine the expression of said gene or the presence of said gene. Applicant has failed to point to by page and line number for support of said determinations. The specification teaches hybridization techniques and the expression of particular proteins, however the specification fails to teach that based solely upon hybridization can an artisan determine the expression of said gene or its presence.

Moreover, there appears to be no teaching of a method wherein the nucleic acid molecule specifically hybridizes to either the transcript of the gene or to the gene.

As to claim 56, only the nucleic acid sequences SEQ ID NO: 12 and 14 are disclosed by the specification as being detection reagents. SEQ ID NO: 15-19, 21-22, 24-25, 27 and 29 are disclosed as being primers. See pages 38-39, 41-42 and 52-53 of the instant specification which recites that SEQ ID NO: 15-19, 21-22, 24-25, 27 and 29 are useable as primers and not as radiolabelled oligonucleotides or detection reagents. Likewise, for claim 57, SEQ ID NO:12 and 14 are disclosed by the specification as being a pair of oligonucleotide primers, but rather detection reagents.

Thus, the claims are not within the scope of the subject matter disclosed within the specification, thus the claims are rejected for claiming new matter.

10. Claims 51-61 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The claims recite an incomplete method.

In particular, claims 51 and 59 are drawn to methods for determining expression of a gene or for determining if a cell contains a gene wherein the gene encodes a human polypeptide that has PI3 kinase activity and a molecular weight of about 110 kD comprising contacting a sample with a nucleic acid molecule which specifically hybridizes to a transcript of said gene at the recited conditions followed by washes and determining said hybridization as a determination of expression of said gene or the presence of said gene. However, the methods are incomplete and lack steps for determining the expression of a gene. For instance, the methods fail to use labeled oligonucleotides or probes in the hybridization steps. The method steps fail to recite

Art Unit: 1645

how the hybridized product is detected. If the method uses RNA there is no step to reverse transcribe and allow for PCR determination of mRNA. No amplification of the product is performed. There is no step for inserting the PCR product into a transfer vector for expression. There is no positively recited step to determine expression or the presence of said gene.

11. Claims 51-61 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The preambles of claims 51 and 59 are drawn to a method for determining expression of a gene or a method for determining if a cell contains a gene respectively. However there are no steps within the method which teach how to determine the expression of a gene or determine if a cell contains a gene. The claims lack a positive recitation of method steps that recite such determinations. For instance there is no step for the amplification of the hybridized nucleic acid molecule by PCR, there is no step for the transient expression of the product, no immunoprecipitation step, there is no step which determines whether the cDNA encodes a protein with a molecular weight of 110 that possesses PI-3 kinase activity. Finally, there is no step which correlates the determination of hybridization to the determination of expression or the presence of said gene.

Therefore, the goal of the preamble is not commensurate with the steps of the method.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is (703) 305-0487. The examiner can normally be reached on Monday through Thursday from 6:30am to 4:00pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Ja-Na Hines *JN*

January 6, 2003

LFS
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